I. The Anticipation Rejections Based On Lee Should Be Withdrawn Because Lee Fails To Disclose Each And Every Element Of The Claimed Invention.

The Examiner rejected claims 1, 2, 6-9, 15-18, 20-21 and 26 under 35 U.S.C. § 102(b) as being anticipated by the Lee. Lee depicts a "multiple-dose syringe gun[] capable of . . . dos[ing] a large number of animals, for example sheep or cattle, with a drug, vaccine or the like." *Lee, col. 1, ll. 7-12.* Dosing a large number of animals requires a substantial quantity of liquid, which is carried in a container attached to the operator's back and fed through a tube to the syringe gun. *Lee, col. 1, ll. 13-16.* The syringe gun has a barrel, a piston, an inlet valve located in the piston, a discharge valve, and a needle mount. *Lee, col. 1, ll. 45-49; col. 7, l. 29.*

Lee does not disclose or suggest the use of an ampoule with the syringe gun. Using an ampoule would defeat the ability of the syringe gun to be fed via the tube leading from the container attached to the operator's back. This is the key feature of Lee that makes it "especially useful in the veterinary field where it is often necessary to dose a large number of animals." *Lee, col. 1, ll. 9-11.* Using an ampoule would also negate the need for the valves, especially the inlet valve. Thus, Lee clearly does not disclose or suggest the use of an ampoule.

Lee also does not disclose or suggest the use of a catheter extending from the outlet of the barrel of the syringe gun to the needle. The syringe gun is for injecting animals like sheep or cattle with a drug or vaccine. Cattle, sheep and other types of livestock are not willing participants for injections. Consequently, livestock animals are run single file through livestock squeeze alleys and chutes so they are restrained when they receive injections. The squeeze alleys and chutes have many bars and/or rails around which a veterinarian must maneuver the syringe gun to inject the animal in the proper injection site. The clearances between the proper injection site and the surrounding bars/rails are usually extremely tight. Increasing the overall length of the syringe gun by running a catheter from the outlet of the barrel of the syringe gun to the needle would significantly decrease the maneuverability and ease of using the syringe gun, thereby reducing its usefulness in the "veterinary field." The need for maneuverability explains why Lee's syringe gun has a valve "housing 6 [that] is integral with [the] needle mount" and is at the immediate end of the syringe gun. *Lee, col. 7, ll. 28-29; FIGS. 1 & 5.* Thus, it is clear that Lee does not disclose or teach the use of a catheter extending from the outlet of a container to a

needle. In fact, Lee teaches away from such an arrangement because trying to implement such an arrangement in the Lee device would make it unsuitable for its intended purpose.

In the syringe gun disclosed by Lee, each valve (i.e., the inlet valve and discharge valve) has a chamber with an inlet orifice, an outlet orifice, and a plate. *Lee, col. 1, ll. 51-52.* A valve's plate will seal the valve's inlet orifice when the plate is "under pressure upon the outlet orifice side of the plate," thereby preventing "any 'back-flow' of liquid or air." *Lee, col. 1, ll. 54-56; col. 2, ll. 49-50.* A valve's plate will unseal "when the pressure on the inlet orifice side of the plate exceeds that on the outlet orifice side to permit liquid to pass from the inlet orifice, through the chamber and out via the outlet orifice." *Lee, col. 1, ll. 57-60.* For instance, when the piston 32 is withdrawn, "the pressure within the barrel 24 on the outlet orifice side of valve disc 43 [(i.e., the valve disc in the inlet valve)] is reduced below that on the inlet orifice side thereof and the valve disc 43 is held on the floor of the chamber" and liquid flows through the inlet valve. *Lee, col. 9, ll. 8-21.* At the same time, "the decrease in pressure in the barrel 24 increases the effectiveness of the seal between the plate 53 [(i.e., the valve disc in the outlet valve)] and lip 56 in discharge valve housing 39 and any backflow of air or liquid through inlet orifice 55 [(i.e., the inlet orifice of the outlet valve)] is prevented. *Lee, col. 9, ll. 21-25.* Likewise, when "the pressure in barrel 24 on the inlet orifice side of plate 53 [(i.e., the valve disc in the outlet valve)] is increased above that on the outlet orifice side," liquid flows through the outlet valve. *Lee, col. 9, ll. 29-36.*

Thus, as far as Lee is concerned, whether or not liquid passes through a valve depends on the pressure differential between the inlet orifice and outlet orifice sides of the plate. A study of Lee reveals that Lee is not concerned with, nor discloses or suggests, a valve that remains closed until the upstream surface of the valve is subjected to at least an opening pressure, which is the pressure that results in a force on the upstream surface of the valve that is equal to or greater than the maximum force that would be exerted on the valve by a fluid column having a height equal to the catheter when extended vertically above the injection area. In other words, Lee does not disclose or suggest a valve that is located along a fluid flow pathway and adapted to permit fluid flow if the force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than the maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended

vertically above the injection area. Also, Lee does not disclose or suggest a valve that permits flow of a fluid drug through the valve from an outlet of a container to an injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is the pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to the height allowed by the catheter when extended.

A. Lee Does Not Disclose The Catheter And Valve As Recited In Independent Claim 1 and, as a result, Fails To Anticipate Claim 1.

Independent claim 1 recites, "a container having a piston for administering said fluid drug through an outlet of said container" and "a catheter connected to the outlet of said container, the catheter having a front end facing away from the outlet and being connected to an injection needle." Independent claim 1 has been amended to recite a valve that "is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is the pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to the height allowed by the catheter when extended." This amendment merely clarifies the claim. It is supported by the specification and figures as filed, for example, at: page 2, lines 11-13; page 8, line 22; page 9, lines 1-2; page 8, lines 13-19; and in FIG. 1. Advantageously, this aspect of the invention addresses accidental discharge: "Where the fluid drug container is located at a greater height than the front end of the catheter or needle, there is the danger that with sufficient height difference between the container and the front end of the catheter, the container could discharge itself as a result of the force of the fluid column." *Specification As Filed, p. 2, ll. 20-21; p. 3, ll. 1-2.*

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. MPEP § 2131. As explained in the previous section, Lee does not disclose or suggest each element of the invention as recited in claim 1. Therefore, Lee fails to anticipate the invention and Applicants respectfully request that the rejection of claim 1 be reconsidered and withdrawn.

B. Lee Does Not Disclose The Ampoule As Recited In Independent Claim 17 and, As A Result, Fails To Anticipate Claim 17.

Amended independent claim 17 recites, "a housing positioned between an outlet of an ampoule containing a fluid drug and an injection needle." As explained in the previous section, Lee does not disclose or suggest an ampoule as recited in claim 17. Further, trying to adapt the syringe gun of Lee to use an ampoule would defeat the primary feature of the syringe gun, which is its ability to be fed via the tube leading from the container attached to the operator's back. It is clear Lee fails to anticipate the invention and Applicants respectfully request that the rejection of claim 17 be reconsidered and withdrawn.

C. Lee Does Not Disclose The Valve As Recited In Independent Claim 26 and, As A Result, Fails To Anticipate Claim 26.

Amended independent claim 26 recites a valve that "is adapted to permit flow of the medication if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area." This amendment clarifies the claim and is supported by the specification and figures as filed, for example, at: page 2, lines 11-13; page 2, lines 20-21; page 3, lines 1-2; page 5, lines 4-6; page 8, lines 13-19; page 8, line 22; page 9, lines 1-2; page 8, lines 13-19; and FIG. 1.

As previously explained, Lee does not disclose or suggest the elements of the invention recited in claim 26. Therefore, Lee fails to anticipate the invention and Applicants respectfully request that the rejection of claim 26 be reconsidered and withdrawn.

D. The Dependent Claims Incorporate All Of The Limitations Of The Independent Claims And, Likewise, Are Not Anticipated By Lee.

Because each dependent claim incorporates all of the limitations of the independent claim from which it depends as well as additional limitations, the above arguments apply *a fortiori* to these claims. Thus, claims 2, 6-9, 15-16, 18, and 20-21 are also in condition for allowance.

E. The New Claims Are Supported By The Specification As Filed And Are Not Anticipated By Lee Or Any Other Prior Art Of Record.

New independent claims 27 and 28 are directed to a device for the metered administration of a medical fluid to an injection area of a patient and recite a valve that is located along a fluid flow pathway and adapted to permit fluid flow if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area. As explained above, it is this aspect of the invention that prevents accidental discharge, and Lee does not disclose or suggest the valve. New independent claim 36 is directed to a method for administering a medical fluid in a metered fashion to an injection area of a patient and is allowable for at least the same reasons.

These new independent claims, and their dependent claims, are supported by the specification and figures as filed. Support may be found in the specification, for example, at: page 2, lines 11-13; page 2, lines 20-21; page 3, lines 1-2; page 5, lines 4-6; page 8, lines 13-19; page 8, line 22; page 9, lines 1-2; page 8, lines 13-19; page 10, line 7; page 10, line 19; and in FIGS. 1 and 2.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

The above amendments generate additional claim fees in the amount of $432.00 and a petition to extend the time to respond by two months (from February 8, 2003 until April 8, 2003) is enclosed herewith. A check in the amount of $614.00 is enclosed ($410 to cover the two-month extension fee; and $204 to cover the extra claims fee), and the Office is also hereby authorized to charge any additional fees associated with this communication or the petition to Deposit Acct. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

Please amend the pending claims as follows.

1. (Twice Amended) A device for the metered administration of a fluid drug to an injection area of a patient, comprising

a) a container having a piston for administering said fluid drug through an outlet of said container,

b) a catheter connected to the outlet of said container, the catheter having a front end facing away from the outlet and being connected to an injection needle, and

c) a valve positioned between the outlet and the injection needle in a flow cross section of the fluid drug, the valve having an inlet end adjacent the outlet and an outlet end adjacent the injection needle, wherein the valve is designed to only permit[s] flow of the fluid drug through the valve from the outlet to the injection needle [when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug] if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is a pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended.

17. (Twice Amended) A device for the metered administration of a fluid drug, comprising:

(a) a housing positioned between an outlet of an ampoule containing a fluid drug and an injection needle; and

(b) a valve positioned in the housing in a flow cross section of the fluid drug, the valve having an inlet end adjacent the ampoule and an outlet end adjacent the injection needle, wherein the housing pretensions the valve at a contact surface thereof against an aperture of a feed line through the housing to the valve, the contact surface sealingly closing the aperture wherein the valve permits flow of the fluid drug through the valve from the inlet end to the outlet

end when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug.

26. (Amended) A device for delivering a fluid medication through a fluid flow pathway to an injection area of a patient, comprising:
a housing:
a container having an outlet, the container received in the housing and containing [a] the fluid [product] medication to be dispensed through the outlet;
a piston carried in the container;
a drive for moving the piston; and
a valve connected to the outlet, wherein the valve [prevents unintentional draining of the fluid product from the container] is adapted to permit flow of the medication if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area.

Please add the following new claims.

27. (New) A device for the metered administration of a medical fluid through a fluid flow pathway to an injection area of a patient, comprising a valve located along the fluid flow pathway and adapted to permit fluid flow if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area.

28. (New) A device for the metered administration of a medical fluid to an injection area of a patient, comprising:

a) a fluid flow pathway in which fluid travels to the injection area; and
b) a valve located along the fluid flow pathway and adapted to permit fluid flow if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force

that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area.

29. (New) The device of claim 28, wherein the fluid flow pathway comprises a catheter.

30. (New) The device of claim 29, wherein the fluid flow pathway further comprises a fluid reservoir.

31. (New) The device of claim 30, wherein the fluid reservoir is an ampoule.

32. (New) The device of claim 30, further comprising a piston movably located within the reservoir.

33. (New) The device of claim 32, further comprising a driven member adapted to move the piston.

34. (New) The device of claim 29, wherein the fluid flow pathway further comprises a needle connected to the catheter and for insertion into the injection area.

35. (New) The device of claim 29, wherein the valve comprises an upstream housing section having a sealing lip, a downstream housing section, and a resilient valve body pretensioned over the sealing lip and annularly clamped between the upstream and downstream housing sections.

36. (New) A method for administering a medical fluid in a metered fashion through a fluid flow pathway to an injection area of a patient, comprising:

a) increasing a pressure that the medical fluid applies to an upstream surface of a valve so the pressure exceeds a valve opening pressure, the valve opening pressure being the pressure which results in a force on the upstream surface of the valve that is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area; and

b) upon reaching the valve opening pressure, flowing medical fluid past the open valve towards the injection area.